

THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Wolfgang HEIL et al.

Confirmation No.: 5622

Serial No.: 09/654,227

Examiner: M. Bahar

Filed: August 31, 2000

Group Art Unit: 1617

Title: PHARMACEUTICAL COMPOSITION FOR USE AS A CONTRACEPTIVE

**SUPPLEMENTAL  
INFORMATION DISCLOSURE STATEMENT  
UNDER 37 C.F.R. §§ 1.56, 1.97 AND 1.98**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

This information disclosure statement is made in accordance with 37 C.F.R. §§ 1.56, 1.97 and 1.98 as follows:

**TIMING AND FEES**

- ☐ Under 37 C.F.R. § 1.97(b), no fee or statement is required for filing this information disclosure statement is filed:
- ☐ within three months of the filing date of a national application other than a CPA under § 1.53(d);
  - ☐ within three months of the actual filing date of the national phase of a PCT application; OR
  - ☐ before the mailing of a first substantive office action (including after filing of an RCE).
- ☒ Under 37 C.F.R. § 1.97(c), this information disclosure statement is filed after the periods specified in 37 C.F.R. § 1.97(b), but before the mailing date of:
- ☒ a final rejection under 37 C.F.R. § 1.113;
  - ☐ termination of prosecution, e.g. Ex Parte Quayle, M.P.E.P § 609(B)(2); OR
  - ☐ a notice of allowance under 37 C.F.R. § 1.311; and

is accompanied by:

- ☐ the statement as specified in 37 C.F.R. § 1.97(e) set out below; OR

☒ a check covering the fee of \$180.00 under 37 C.F.R. § 1.17(p).

☐ Under 37 C.F.R. § 1.97(d), this information disclosure statement is filed after the mailing date of the following actions which have not been withdrawn:

- ☐ a final action under 37 C.F.R. § 1.113;
- ☐ termination of prosecution, e.g. Ex Parte Quayle, M.P.E.P § 609(B)(2); OR
- ☐ a notice of allowance under 37 C.F.R. § 1.311;

AND is filed on or before payment of the issue fee; AND is accompanied by:

- ☐ the statement as specified in 37 C.F.R. § 1.97(e) as set forth below, and the fee of \$180.00 under 37 C.F.R. § 1.17(p).

**STATEMENTS UNDER 37 C.F.R. 1.97(e)**

- ☐ Each item of information contained in this information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application having a mailing date not more than three months prior to the filing date of this information disclosure statement; or
- ☐ No item of information contained in this information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and to the knowledge of the undersigned attorney after making reasonable inquiry, no item of information contained in this information disclosure statement was known to any individual designated in 37 C.F.R. § 1.56(c) more than three months prior to the filing date of the information disclosure statement.

**CITED MATERIALS**

- ☐ Copies of materials listed but not attached were cited in benefit (35 U.S.C. § 120) ancestor application Serial No. \_\_\_\_\_, on Form 892 by the Examiner and/or Form 1449 by the applicant; see 37 C.F.R. § 1.98(d).
- ☐ Copies of materials listed but not attached were cited in an international search report dated \_\_\_\_\_.
- ☒ Copies of the materials listed are attached (except for the foregoing).

**NON-ENGLISH LANGUAGE REFERENCES**

- ☐ An English-language search report or equivalent paper from a foreign patent office is provided indicating the relevance of the cited reference(s).
- ☐ A foreign-language search report from a foreign patent office is provided, and pertinent parts are translated substantively below:

X = document of particular relevance when it is taken alone  
Y = document of particular relevance when it is combined with another such document  
A = document defining the general state of the art  
O = non-written disclosure  
P = intercalated document  
T = document cited to understand the theory or principle underlying the invention  
E = patent document which has the benefit of a date earlier than the filing date and which was published only on or after this filing date  
D = cited in the application  
L = cited for another reason  
& = publication of member of same patent family

☐ Translation of other relevant information on foreign search report

#### **OTHER INFORMATION**

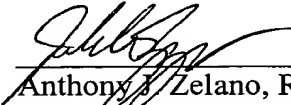
The 21 slides of the C1 document were projected on a screen during an oral presentation given by Dr. Johannes Tack in Germany in 1988. Dr. Tack was an employee of Schering AG, the assignee, at the time. (Dr. Tack has recently been determined to be an inventor on this application. Inventorship correction papers will be filed soon.) No printed copies or other tangible forms of the slides were distributed at this lecture or at any other time, before or after. Applicants submit that these circumstances do not give rise to creation of any prior art. A lecture in a foreign country is not prior art. A lecture is also not a printed publication. Slides shown at a lecture are also not prior art when, as here, copies of the slides were not disseminated before, during or after the lecture and hence were not available or accessible to the public. See, for example, Regents of the University of California v. Howmedica, Inc., 210 USPQ 727 (D. N.J. 1981), aff'd, 676 F.2d 687 (3<sup>rd</sup> Cir. 1982) (which Chisum [Chisum on Patents, §3.04[2], Note 6] cites for the proposition that "slides accompanying a lecture by the inventor did not constitute a printed publication where slides were not otherwise made available"); and Hybritech, Inc. v. Abbott Laboratories, 4 USPQ2d 1001 (C.D. Cal. 1987), aff'd, 7 U.S.P.Q.2d 1191 (Fed. Cir. 1988) ("Absent any evidence that the copies [of an oral speech] were distributed at the speech or made available on request after the speech, I do not believe that the ... reference amounts to a publication...." quote from same Chisum cite quoting the decision).

The Sattar document, published before applicants' filing date, shows that it was known in the art that micronized ethinyl estradiol was useful in compositions and methods for contraception. See, e.g., paragraph bridging pages 10-11. In fact, assignee had sold micronized ethinyl estradiol in the U.S. for several years before the filing of this application in oral contraceptive compositions not containing drospirenone.

**PAYMENT OF FEES DUE (IF ANY):**

- ☒ A check for \$180.00 covering the fee identified above is attached.
- ☐ Please charge to Deposit Account No. 13-3402 \$\_\_\_\_\_ for the fee identified above.
- ☒ The Commissioner is hereby authorized to charge or credit any overpayment to Deposit Account No. 13-3402, two copies of this paper are attached for this purpose.

Respectfully submitted,



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Attorney Docket No.: PLOVIN-1A

Date: February 26, 2004

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## INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Sheet 1 of 1

### Complete if Known

|                        |                      |
|------------------------|----------------------|
| Application Number     | 09/654,227           |
| Filing Date            | August 31, 2000      |
| First Named Inventor   | Wolfgang HEIL et al. |
| Group Art Unit         | 1617                 |
| Examiner Name          | M. Bahar             |
| Attorney Docket Number | PLOVIN-1A            |

### U.S. PATENT DOCUMENTS

| Examiner<br>Initials * | Cite No. <sup>1</sup> | U.S. Patent Document |                                      | Name of Patentee or Applicant<br>of Cited Document | Date of Publication of Cited Document<br>MM-DD-YYYY |
|------------------------|-----------------------|----------------------|--------------------------------------|--|---|
|                        |                       | Number               | Kind Code <sup>2</sup><br>(if known) |  |   |
|                        | A1                    |                      |                                      |  |   |
|                        | A2                    |                      |                                      |  |   |
|                        | A3                    |                      |                                      |  |   |
|                        | A4                    |                      |                                      |  |   |
|                        | A5                    |                      |                                      |  |   |
|                        | A6                    |                      |                                      |  |   |
|                        | A7                    |                      |                                      |  |   |

### FOREIGN PATENT DOCUMENTS

| Examiner<br>Initials * | Cite No. <sup>1</sup> | Foreign Patent Document |                     |                                      | Name of Patentee or Applicant of<br>Cited Document | Date of Publication of<br>Cited Document<br>MM-DD-YYYY | Pages, Columns, Lines,<br>Where Relevant<br>Passages or Relevant<br>Figures Appear | T <sup>6</sup> |
|------------------------|-----------------------|-------------------------|---------------------|--------------------------------------|--|--|--|----------------|
|                        |                       | Office <sup>3</sup>     | Number <sup>4</sup> | Kind Code <sup>5</sup><br>(if known) |  |  |  |                |
|                        | B1                    |                         |                     |                                      |  |  |  |                |
|                        | B2                    |                         |                     |                                      |  |  |  |                |
|                        | B3                    |                         |                     |                                      |  |  |  |                |
|                        | B4                    |                         |                     |                                      |  |  |  |                |
|                        | B5                    |                         |                     |                                      |  |  |  |                |
|                        | B6                    |                         |                     |                                      |  |  |  |                |
|                        | B7                    |                         |                     |                                      |  |  |  |                |

### NON PATENT LITERATURE DOCUMENTS

| Examiner<br>Initials * | Cite No. <sup>1</sup> | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.              | T <sup>2</sup> |
|------------------------|-----------------------|--|----------------|
|                        | C1                    | An invitation (one page) for and 21 slides shown in an oral presentation held on February 17, 1988 in Berlin, Germany, entitled "Studies on pH-dependent Isomerization of Pregnene-17,21-Carbolactones," by Johannes W. Tack. (Original in German with English translation.) |                |
|                        | C2                    | Sattar, et al., J.Clin.Endocrin.&Metab., Vol. 82, No. 8, 1483-2491 (1997).   |                |
|                        | C3                    |  |                |

Examiner  
Signature

Date  
Considered

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Unique citation designation number. <sup>2</sup> See attached Kinds of U.S. Patent Documents. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.